

ENVIRONMENTAL ASSESSMENT

1. **Date:** September 12, 2022
2. **Name of Applicant:** Avient Corporation, including its subsidiaries ColorMatrix Corporation, ColorMatrix Europe Ltd., and ColorMatrix Europe BV
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All communications on this matter are to be sent in care of Counsel for Notifier:

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4. **Description of the Proposed Action**

The action requested in this Notification is to establish a clearance for the food-contact substance (FCS), titanium nitride (CAS Reg. No. 25583-20-4), which has the molecular formula TiN, when used at levels of up to 25 ppm in polyethylene terephthalate (PET).

Titanium nitride is intended for use in PET that will contact food under Conditions of Use A (“High Temperature, heat sterilized or retorted”) through H (“Frozen or refrigerated storage: ready prepared foods intended to be reheated in container at time of use”) and J (“Cooking (*e.g.*, baking or browning) at temperatures exceeding 121°C”). Titanium nitride is not intended for use in PET that contacts infant formula and human milk. Titanium nitride is intended to improve polymer reheat uptake.

Food-contact materials containing the FCS will be utilized in patterns corresponding to the national population density and will be widely distributed across the country. Therefore, it is anticipated that disposal of the FCS will occur nationwide, with the material being land disposed, combusted, or recycled in quantities similar to those reported for municipal solid waste generally.¹ According to the U.S. Environmental Protection Agency’s 2018 update regarding

¹ Advancing Sustainable Materials Management: Facts and Figures 2018, U.S. Environmental Protection Agency, available at https://www.epa.gov/sites/production/files/2020-11/documents/2018_ff_fact_sheet.pdf (last accessed July 28, 2022). Importantly, the PET industry has made significant commitments to achieving 100% recyclable plastic packaging within the next 5 – 10 years. See National Association for PET Container Resources (NAPCOR), Brand Commitments, available at <https://napcor.com/why-pet/brand-commitments/> (last accessed July 28, 2022).

municipal solid waste in the United States, it is estimated that, of the 292.36 million tons of municipal solid waste (MSW) generated in 2018, 50.0% of municipal solid waste generally was land disposed, 23.6% was recycled, 11.8% was combusted, 8.5% was composted, and 6.1% was handled through other food management pathways.² As the FCS is expected to be primarily disposed of through recycling, combustion, or land-filling (*i.e.*, not composted or handled through other food management pathways), we recalculate the disposal pattern based on only the quantities of MSW that are land disposed, recycled, or combusted. On this basis, we estimate that 13.8% of food-contact materials containing the FCS will be combusted annually.³

5. Identification of Substance that is the Subject of the Proposed Action

The FCS that is the subject of this Notification is titanium nitride (CAS Reg. No. 25583-20-4), which has the molecular formula TiN.

Chemical Abstracts Service (CAS) Name: Titanium Nitride

CAS Registry Number: 25583-20-4

Structural Formula: Ti≡N

Physical Description of FCS:

Physical Form: Black powder

Particle Size: < 20 nm

Melting Point: Approximately 2,950°C

Solubility: The FCS is expected to be insoluble in water, ethanol, hydrochloric acid, sulfuric acid, and nitric acid at ambient temperature.⁴

6. Introduction of Substances into the Environment

Under 21 C.F.R. § 25.40(a), an environmental assessment ordinarily should focus on relevant environmental issues relating to the use and disposal from use, rather than the production, of FDA-regulated materials. Nonetheless, the Notifier asserts that there are no extraordinary circumstances that would indicate the potential for adverse environmental impacts resulting from the manufacture of the FCS such as: (1) unique emission circumstances not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal, State, or local environmental agencies where the emissions may harm the environment; (2) the proposed action threatening a violation of Federal, State, or local environmental laws or requirements; or (3) production associated with a proposed action that may adversely affect a species or the critical habitat of a species determined under the

² *Id.*

³ 11.8% Combusted ÷ (11.8 % combusted + 23.6 % recycled + 50% land disposed) = 13.8% combusted.

⁴ See *Gmelin Handbuch der anorganischen Chemie*: System Nr. 41 (1951) Titan, pp. 272-285.

Endangered Species Act or the Convention on International Trade in Endangered Species of Wild Fauna and Flora to be endangered or threatened, or wild fauna or flora that are entitled to special protection under some other Federal law. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

No significant adverse environmental release is expected upon the use of the subject FCS in food-contact materials. In these applications, the FCS (*i.e.*, an additive to PET) is expected to be entirely incorporated into the finished food-contact article and is expected to remain with these materials throughout the use of the FCS in the food-contact applications and use/disposal by the consumer. Any waste materials generated in this process, *e.g.*, plant scraps, are expected to be disposed of as part of the packaging manufacturer's overall nonhazardous solid waste in accordance with established procedures.

Disposal by the ultimate consumer of food-contact materials containing the subject FCS will be by conventional rubbish disposal (*i.e.*, sanitary landfill or incineration) or recycling. The National Association for PET Container Resources (NAPCOR) estimates that 28% of PET bottles were recycled in 2019.⁵ ASTM standard number D7611 "Standard Practice for Coding Plastic Manufactured Articles for Resin Identification" provides a guide for plastics manufacturers to mark the final plastic article with an identification code that informs users/recyclers of the identity of the resin with which the final plastic article is made.⁶ We therefore anticipate the PET manufactured containing the FCS would be so marked and thus coded for identification as PET.

The FCS consists of titanium and nitrogen. Upon combustion of the FCS, the titanium can react with oxygen to form inert titanium dioxide and the nitrogen may react with oxygen to form the greenhouse gas (GHG) nitrous oxide (N₂O). Based on the elemental composition of the FCS, the worst-case release of nitrous oxide has been calculated in a confidential appendix to the Environmental Assessment. The concentrations of nitrous oxide in the environment will not be significantly altered by the proper incineration of the FCS in the amounts utilized for food packaging applications.

To evaluate the significance of the environmental impact, we considered whether the action threatens a violation of Federal, State, or local laws or requirements imposed for the protection of the environment. GHG emissions from MSW combustion facilities are regulated under 40 C.F.R. § 98.2. The expected carbon dioxide equivalent emissions are below 25,000 metric tons on an annual basis (*see* Confidential Attachment to Environmental Assessment). As the estimated GHG emissions are well below the threshold for mandatory reporting, no significant adverse environmental impacts are anticipated from combustion of food-contact materials containing the FCS in MSW combustion facilities.

EPA regulations require all solid-waste landfill units and lateral expansions of existing units to have composite liners and leachate collection systems to prevent leachate from entering

⁵ See National Association for PET Container Resources (NAPCOR), *NAPCOR Releases 2019 PET Recycling Report: RPET Content in Bottles and Containers Grow*, available at: <https://napcor.com/news/4970-2/> (last accessed July 28, 2022).

⁶ ASTM, Standard Practice for Coding Plastic Manufactured Articles for Resin Identification, 2020. D7611/D7611M-20.

ground and surface water and to have ground-water monitoring systems (40 C.F.R. Part 258 and Appendix 2). These requirements are enforced by state solid-waste management programs. Therefore, based on MSW landfill regulations preventing leaching and state enforcement of these requirements, the food contact substance is not expected to reach aquatic or terrestrial environment when disposed via landfill.

7. Fate of Emitted Substances in the Environment

A. Air

No significant effect on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of the FCS. Because the FCS is an inorganic compound that melts at approximately 2950°C, the FCS is not expected to readily volatilize. Further, the FCS is unlikely to combust. As indicated above in Item 6, even if the FCS were to combust, no significant adverse environmental impacts are anticipated resulting from combustion of the FCS in MSW combustion facilities. Therefore, combustion of the FCS will not significantly alter the emissions from properly operating municipal solid waste combustors, and the incineration of food-contact materials containing the FCS will not cause municipal solid waste combustors to threaten a violation of applicable emissions laws and regulations. *See Confidential Attachment for additional details.*

B. Water

No significant effects on the concentrations of and exposures to any substances in fresh water, estuarine, or marine ecosystems are anticipated due to the proposed use of the FCS. The fate of finished food-contact materials manufactured with the FCS in the aqueous environment does not need to be addressed because no significant introductions of substances into the environment were identified in Item 6.

C. Land

Considering the factors discussed above, no significant effects on the concentrations of and exposures to any substances in terrestrial ecosystems are anticipated as a result of the proposed use of the subject FCS. In particular, the insolubility of the FCS and its complete incorporation into PET are expected to result in virtually no leaching of the FCS under normal environmental conditions when these food contact materials are disposed. Furthermore, the estimated production of finished food-contact articles with the FCS, as discussed in the corresponding confidential attachment, precludes any substantial release to the environment of its components. Thus, there is no expectation of any meaningful exposure to terrestrial organisms of these substances as a result of the proposed use of the FCS.

Considering the foregoing, we respectfully submit that there is no reasonable expectation of a significant impact on the concentration of any substance in the environment due to the proposed use of the FCS in the manufacture of food-contact materials.

8. Environmental Effects of Released Substances

No information is needed to address the environmental effects of substances released into the environment as a result of the use and disposal of the subject substance in landfills and by combustion because, as discussed under Item 6 above, only very small quantities of substances,

if any, are expected to be introduced into the environment due to the intended use of the FCS. The use and disposal of the subject substance in landfills or by combustion are not expected to threaten a violation of applicable laws and regulation, *e.g.*, the Environmental Protection Agency's regulations in 40 C.F.R. Part 60 ("Standards of performance for new stationary sources") that pertain to municipal solid waste combustors and Part 258 that pertain to landfills.

9. Use of Resources and Energy

As is the case with other food-contact materials, the production, use, and disposal of the FCS involve the use of natural resources. However, the use of the subject FCS as an additive in food-contact materials is not expected to result in a net increase in the use of energy and resources because it is used at a very low level (25 ppm) and can be used in place of other additives to PET, such as carbon black (which can serve as a reheat additive in PET processing as does TiN).

The replacement of other additives (*e.g.*, carbon black) by the subject FCS in PET is not expected to have any significant adverse impact on the use of energy and resources. Articles and packaging materials produced from PET containing the FCS are expected to be disposed of according to the same patterns when used in place of currently marketed materials. The presence of the FCS at low levels in the PET matrix is not expected to have any significant adverse impact on the recyclability of PET.

10. Mitigation Measures

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of food-contact materials fabricated containing the FCS. Thus, the use of the FCS as proposed is not reasonably expected to result in any new environmental problem requiring mitigation measures of any kind.

11. Alternatives to the Proposed Action

No significant potential adverse environmental effects are identified herein that would necessitate alternative actions to those proposed in this Notification. The alternative of not approving the action proposed herein would simply result in the continued use of the materials that the subject FCS would otherwise replace (*e.g.*, carbon black); such action would have no anticipated environmental impact.

12. List of Preparers


Catherine R. Nielsen, Partner, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001. Ms. Nielsen has a J.D., with over 30 years of experience drafting food additive petitions and Food Contact Notification (FCN) submissions and environmental assessments.

Kristin P. Wiglesworth, Ph.D. in Chemistry, Staff Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001. Dr. Wiglesworth has over 5 years of experience performing evaluations relating to all aspects of preparing FCNs, 16 years of total experience in FDA regulated industries.

13. Certification

The undersigned official certifies that the information provided herein is true, accurate, and complete to the best of her knowledge.

Date: September 12, 2022


Catherine R. Nielsen
Counsel for Notifier

14. List of References

1. *Advancing Sustainable Materials Management: Facts and Figures 2018*, U.S. Environmental Protection Agency, available at: https://www.epa.gov/sites/production/files/2020-11/documents/2018_ff_fact_sheet.pdf (last accessed July 28, 2022).
2. *National Association for PET Container Resources (NAPCOR), Brand Commitments*, available at: <https://napcor.com/why-pet/brand-commitments/> (last accessed July 28, 2022).
3. *Gmelin Handbuch der anorganischen Chemie*: System Nr. 41 (1951) Titan, pp. 272-285.
4. National Association for PET Container Resources (NAPCOR), *NAPCOR Releases 2019 PET Recycling Report: RPET Content in Bottles and Containers Grow*, available at: <https://napcor.com/news/4970-2/> (last accessed July 28, 2022).
5. ASTM, Standard Practice for Coding Plastic Manufactured Articles for Resin Identification, 2020. D7611/D7611M-20.

15. Attachments

1. Confidential Attachment – Attachment 10